Remarks

Claims 39, 72, 74, 77 and 81 have been amended. Claims 43 and 73 have been cancelled without prejudice or disclaimer and with the understanding that Applicants may pursue the subject matter of the cancelled claims in a continuation application. New claim 84 has been added.

The amendment to claims 39 and 72 specifies ethanol as the alcohol and in a proportion of about 1 to about 50 percent by weight and excludes the presence of a steroid. Support for this amendment may be found in Applicants' specification at, *inter alia*, page 4, lines 14-15; page 5, line 11; and page 6, lines 6-10.

The amendment to claims 74, 77 and 81 simply reflects the cancellation of claim 72 upon these claims originally depended.

New claim 84 removes propylene carbonate as a component of the claimed composition and finds support, *inter alia*, in claim 39 and generally throughout the specification.

Accordingly, no new matter has been introduced by any of the amendments or the new claim.

1. Rejection under 35 U.S.C. § 103(a)

A. Sun

Claims 39-62, 64, 66-71, 74, 75, 77-80 and 83 are rejected as allegedly unpatentable over U.S. Patent No. 5,993,787 to Sun *et al.* ("Sun"). The Examiner asserts that Sun teaches anhydrous topical preparations that comprise propylene carbonate, one or more short chain alcohols and/or glycols, glycerol and an active ingredient. The Examiner cites a section of the Sun specification wherein ketoconazole is disclosed as a suitable active ingredient and other sections where additional components such as pigments, ascorbic acid, BHT, chelating agents and hydroxypropyl cellulose are allegedly taught to be useful as well. The Examiner acknowledges that Sun does not explicitly disclose the particular combination of components claimed by Applicants but asserts that absent a showing of unexpected results, it would have been obvious to a person of ordinary skill in the art to prepare the composition claimed by Applicants.

Applicants respectfully submit that Sun does not render Applicants' claimed invention obvious for at least the following reasons. Sun teaches compositions containing, *inter alia*, one or more short carbon chain alcohols and/or glycols including ethanol, isopropyl alcohol, propylene glycol, butylene glycol, hexylene glycol, polyethylene glycol, methoxpolyethylene glycol and their derivatives (col. 5, lines 25-29, emphasis added). Based on this description in Sun, literally hundreds of compositions would

be possible. Exemplary products 1, 2 and 3 are described as "formulated according to the present invention", but they each contain a higher amount of ethanol (55.87 wt %) than is allowed by Applicants' claims as amended. Therefore, there is no motivation for a person of ordinary skill in the art to select Applicant's particular claimed composition from the list of components described in Sun.

Further, Applicant's claimed compositions show unexpected results. The Cauwenbergh declaration, submitted herewith under 37 C.F.R. 1.132 (and originally submitted in copending Application No. 09/562,376), testifies as to the experimentally determined anti-inflammatory superiority of an anhydrous alcohol-based gel formulation of ketoconazole lacking a steroidal component compared to an otherwise identical anhydrous alcohol-based gel formulation of ketoconazole containing a steroidal component (see the graphs depicting comparisons of global scores and combination scores). Such results are completely unexpected and were not previously contemplated in Sun. In fact, Sun teaches away from compositions that do not include steroidal agents by listing suitable steroidal anti-inflammatory agents (see, *e.g.*, col. 6, line 58 to col. 7, line 16).

The Cauwenbergh declaration also documents the significantly lower cumulative irritation experienced by a patient who is being treated with Applicants' claimed anhydrous alcohol-based gel formulation of ketoconazole lacking a steroidal component compared to a patient being treated with an aqueous formulation of ketoconazole (Nizoral®) also lacking a steroidal component. Such results contradict the predictions based on the conventional wisdom of a skilled artisan that an anhydrous alcohol-based formulation of a medicament should be significantly more irritating to skin than a water-based formulation of the same medicament.

The Cauwenbergh declaration also documents the superior overall efficacy of the anhydrous alcohol-based gel formulation of ketoconazole lacking a steroidal component in treating patients afflicted with seborrheic dermatitis compared to the aqueous formulation of ketoconazole (Nizoral®) also lacking a steroidal component.

Sun does not teach or suggest the above-discussed unexpected results associated with Applicants' claimed anhydrous alcohol-based gel composition.

For at least the above-discussed reasons, Sun cannot therefore render obvious Applicants' claimed anhydrous compositions and Applicants respectfully request that this rejection be withdrawn.

B. Sun in view of Kabara

Claims 63, 65, 72 and 73 are rejected as allegedly unpatentable over Sun in view of U.S. Patent 5,208,257 to Kabara ("Kabara"). The Examiner relies on Kabara for its alleged teaching of chelating agents such as citric acid.

In light of the arguments presented in section A above, Applicants submit that Sun does not render Applicants' claimed invention obvious. Kabara cannot remedy these deficiencies present in Sun. Accordingly, Applicants respectfully request that this rejection be withdrawn.

C. Sun in view of Thornfeldt

Claims 76, 81 and 82 are rejected as allegedly unpatentable over Sun in view of U.S. Patent 5,231,087 to Thornfeldt ("Thornfeldt"). The Examiner relies on Thornfeldt for its alleged teaching of the treatment of seborrheic dermatitis.

In light of the arguments presented in section A above, Applicants submit that Sun does not render Applicants' claimed invention obvious. Thornfeldt cannot remedy these deficiencies present in Sun. Accordingly, Applicants respectfully request that this rejection be withdrawn.

2. Double Patenting

A. U.S. Patent 6,238,683

Claim 39-73 are rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-3, 8-16, 22, 25 and 26 of U.S. Patent 6,238,683 ("the '683 patent"). The Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from each other.

Applicants intend to file a Terminal Disclaimer over U.S. Patent 6,238,683 once allowable claims in the subject application have been identified.

B. U.S. Patent Application No. 09/562,376

Claims 39-83 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claimed 48-53, 56-62 and 86-118 of copending Application No. 09/562,376 ("the '376 application"). The Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from each other.

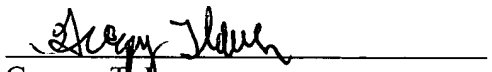
Applicants intend to file a terminal disclaimer over the '376 application once allowable claims in the '376 application are identified.

3. Conclusion

The foregoing amendments and remarks are being made to place the application in a condition for allowance. Applicant respectfully requests reconsideration and the timely allowance of the pending claims. Should the Examiner find that an interview would be helpful to further prosecution of this application, she is invited to telephone the undersigned at his convenience.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which my be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. 1.136(a)(3).

Respectfully submitted
Morgan, Lewis & Bockius LLP



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Dated: November 20, 2006

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